

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LAVONIA BOSTIC	:	CIVIL ACTION
	:	
v.	:	
	:	
ETHICON INC. AND	:	
JOHNSON & JOHNSON	:	NO. 20-6533

**MEMORANDUM**

**Padova, J.**

**March 29, 2022**

Plaintiff Lavonia Bostic filed this action against Defendants Ethicon Inc. and Johnson & Johnson, alleging that she suffered injuries after being implanted with the Gynecare TVT pelvic mesh product that was manufactured, sold, and distributed by Defendants. Defendants have moved to dismiss her First Amended Complaint (“Complaint”). For the following reasons, the Motion to Dismiss is granted in part and withdrawn in part.

**I. FACTUAL BACKGROUND**

The Complaint alleges the following facts. Bostic was implanted with the Ethicon Gynecare TVT pelvic mesh product (the “TVT product”) to treat stress urinary incontinence (“SUI”) by Dr. Carmen J. Sultana (“Plaintiff’s implanting physician”) at Thomas Jefferson University Hospital in Philadelphia.<sup>1</sup> (Comp. ¶¶ 2, 52.) The TVT product, like most pelvic mesh products, is made from polypropylene mesh, which is a type of plastic. (*Id.* ¶¶ 3, 13, 15.) Plaintiff developed complications from the TVT product, which include “mesh complications necessitating a revision procedure, sling dysfunction, mesh contracture and shrinkage, urinary hesitancy,

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<sup>1</sup> The Complaint alleges that the implantation occurred on August 31, 2011. However, Plaintiff states in her response to the Motion to Dismiss that she was implanted with the TVT product on October 26, 2010 and had revision surgery to remove it on August 30, 2011. Accordingly, Plaintiff’s actual implantation date is unclear.

difficulty voiding or urinary retention, mixed urinary incontinence, chronic pelvic pain, dyspareunia, a vaginal bulge, and stress and anxiety. (Id. ¶ 4.) Ethicon, Inc. is part of a business unit of Johnson & Johnson that designed, promoted, marketed, distributed, and sold the TVT product. (Id. ¶ 5.)

Surgical mesh is a medical device that is used to repair weakened or damaged tissue. (Id. ¶ 13.) “It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material.” (Id.) Gynecologists began using surgical mesh products for the surgical repair of prolapsed organs in the 1970s. (Id. ¶ 11.) In the 1990s, gynecologists began to use surgical mesh to treat pelvic organ prolapse (“POP”) and SUI. (Id.) Defendants manufacture the TVT product, which is a Class II medical device, for women who suffer from SUI “as a result of the weakening [of] or damage caused to the walls of the vagina.” (Id. ¶¶ 12, 14.) To treat SUI, surgical mesh is used to reinforce the weakened vaginal wall and support the urethra. (Id. ¶ 13.) The TVT product is marketed as a way to correct SUI with a “minimally invasive procedure” that causes “minimal local reactions, minimal tissue trauma and minimal pain.” (Id. ¶ 12.)

Polypropylene mesh is biologically incompatible with human tissue. (Id. ¶ 15.) A large number of the people who are inserted with the TVT product experience “host defense response” in which their ““pelvic tissue[] promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain.” (Id. ¶ 16.) The “host defense response” can also cause “painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to adverse reactions to the mesh.” (Id.) In addition, TVT products which contain collagen cause “hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction.” (Id. ¶ 17.)

Defendants' TVT products which contain collagen disintegrate after implantation causing adverse tissue reactions and infection. (Id.) Moreover, cross linked collagen hardens body tissues. (Id.) In addition, insertion of the TVT product in the female body "creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities." (Id. ¶ 18.)

The FDA approved the marketing of the TVT product for use in the treatment of SUI in 1997 under the 510(k) approval process. (Id. ¶ 19.) The 510(k) approval process, "provides for marketing of a medical device if the device is deemed 'substantially equivalent' to other predicate devices marketed before May 28, 1976." (Id.) The 510(k) approval process does not require a formal review for safety or efficacy and no such review was conducted with respect to the TVT product. (Id.)

Defendants marketed the TVT product to the medical community and to patients "as a safe, effective, reliable medical device; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, including [SUI], and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing pelvic mesh products." (Id. ¶ 21.) Defendants sold the TVT product to the medical community and to patients "through carefully planned, multifaceted marketing campaigns and strategies," including aggressive marketing to health care providers at medical conferences, hospitals, and private offices, using cash and non-cash benefits to health care providers. (Id. ¶ 22.) Defendants also marketed the TVT product through documents, patient brochures, and websites, which exaggerated and created "misleading expectations as to the safety and utility of the TVT product." (Id. ¶ 23.) Defendants also engaged in direct-to-consumer marketing for the TVT product. (Id.)

On October 20, 2008, the FDA issued a Public Health Notification that described more than 1000 adverse events that had been reported over the previous three-year period related to

pelvic mesh products, including Defendants' TVT product. (*Id.* ¶¶ 26-27.) On July 13, 2011, the FDA issued a Safety Communication warning of serious complications from pelvic mesh products, including the TVT product. (*Id.* ¶ 28.) The FDA stated that ““serious complications associated with surgical mesh for transvaginal repair of POP are not rare.”” (*Id.*) The Safety Communication warning also noted that “[m]esh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain.”” (*Id.* ¶ 29 (alteration in original).) The Safety Communication also indicated that the benefits of using pelvic mesh products could be outweighed by the risks of using those products: ““it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risks.”” (*Id.* ¶ 30.)

At the same time that it released the Safety Communication, the FDA released a White Paper titled “Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse.” (*Id.* ¶ 31.) The White Paper noted that “[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh.”” (*Id.* (alteration in original).) The White Paper also stated that the FDA ““has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risks.”” (*Id.* ¶ 32.) The White Paper also noted that the mesh products “are associated with serious adverse events” and that “POP can be treated successfully without mesh.” (*Id.* ¶ 33.) The White Paper

further stated “that the FDA ‘ha[d] identified serious safety and effectiveness concerns over the use of surgical mesh for transvaginal repair of pelvic organ prolapse.’” (Id.)

On August 25, 2011, Public Citizen petitioned the FDA for a ban on the use of the TVT product in pelvic repair procedures. (Id. ¶ 34.) In December 2011, a joint committee of the American College of Obstetricians and Gynecologists (“ACOG”) and the American Urogynecologic Society (“AUGS”) “identified physical and mechanical changes to the TVT transvaginal mesh inside the body as a serious complication associated with transvaginal mesh” that could cause contraction, retraction, or shrinkage and require surgical repair; the joint committee also noted that some of the pain caused by the condition “appears to be intractable.” (Id. ¶ 35.) The ACOG/AUGS Joint Committee also recommended that “[p]elvic organ prolapse vaginal mesh repair . . . be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk.” (Id. ¶ 36 (first alteration in original).) “In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.” (Id. ¶ 39.) “On April 16, 2019, the FDA ordered all transvaginal POP device manufacturers, including Defendants, to stop selling and distributing these products immediately.” (Id. ¶ 40.) The FDA had “concluded that these products do not have a reasonable assurance of safety and effectiveness.” (Id.)

Defendants marketed the TVT product as a safe medical device even though they knew that “the product was not safe for its intended purposes” and that it would and did cause serious medical problems and catastrophic injuries. (Id. ¶ 53.) Defendants hid the magnitude and frequency of these problems from physicians. (Id.) Defendants intentionally misrepresented and concealed facts regarding the defective nature of the TVT product from Plaintiff and her physicians so that they would request and purchase the TVT product, and Plaintiff and her implanting

physician justifiably relied on Defendants' misrepresentations to Plaintiff's detriment. (*Id.* ¶¶ 54-55.) Plaintiff and her physicians were not aware of the facts about the TVT product and, if they had been, they would not have relied on Defendants' representations about the safety and efficacy of the TVT product or used the TVT product to treat Plaintiff's SUI. (*Id.* ¶ 56.) Defendants made misrepresentations about the TVT product to Plaintiff's implanting physician at the hospital where she conducted Plaintiff's implant surgery, at her office or practice, at Defendants' training or educational sessions, and at professional organization meetings and presentations. (*Id.* ¶ 58.) Defendants' misrepresentations include "statements that the TVT device is 'safe and effective', 'does not cause chronic conditions', and 'does not degrade or otherwise deform.'" (*Id.*) However, "the TVT product has high rates of failure, injury, and complications, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damages to a significant number of women, including Plaintiff." (*Id.* ¶ 59.)

The TVT products have the following defects: (a) they use polypropylene, which causes serious and permanent injuries; (b) they are designed to be inserted into an area of the body that is full of blood vessels and nerves, leading to excessive blood loss and permanent nerve injury; (c) the design results in migration, contraction and shrinkage of the mesh inside the body, which causes serious and permanent injury; (d) the design leads to plastic deformation during implantation and causes the mesh to be encapsulated in a rigid scar plate which results in chronic pain; (e) the TVT product tends to become rigid and inflexible, causing discomfort and pain with normal daily activities; (f) the TVT product degrades or fragments, causing chronic inflammation and chronic infections; (g) inflammatory responses to the collagen in the TVT product leads to chronic inflammatory response, pain and infections; (h) the collagen tends to disintegrate after

implantation, causing pain; (i) the TVT product tends to harden in the body; and (j) surgeons are unable to treat many of these conditions because the mesh becomes integrated into the surrounding pelvic tissue and cannot be safely removed. (Id. ¶ 60.) Defendants failed to warn Plaintiff and her health care providers about these defects and the risk of painful conditions that could result from these defects. (Id. ¶ 61.)

The Complaint asserts 14 causes of action: negligence (Count I); design defect, based on both negligence and strict liability (Count II); manufacturing defect, based on both negligence and strict liability (Count III); failure to warn, based on both negligence and strict liability (Count IV); common law fraud (Count V); breach of express warranty (Count VI); breach of implied warranty (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); gross negligence (Count XI); fraudulent concealment (Count XII); unjust enrichment (Count XIII); and punitive damages (Count XIV). Defendants move to dismiss the Complaint in its entirety pursuant to Federal Rule of Civil Procedure 12(b)(6) on the grounds that it is an impermissible “shotgun pleading.” Defendants also initially moved to dismiss each of Plaintiff’s individual claims on the ground that the Complaint fails to state claims upon which relief may be granted. Defendants have withdrawn those arguments with respect to the following Counts: negligence (Count I) (except with respect to Plaintiff’s negligent manufacturing claims); negligent design defect (Count II); negligent failure to warn (Count IV); and negligent infliction of emotional distress (Count X). (See Defs.’ Reply at 5.) Defendants ask that Plaintiff be required to file an amended complaint alleging Counts I, II, IV and X with additional specificity and Plaintiff has agreed to that request. (See 12/2/21 Hr’g Tr. at 3-12.) In addition, the parties agreed, at the Hearing held in this action on December 2, 2021, to the dismissal

of Plaintiff's claims for gross negligence and punitive damages (Counts XI and XIV ). (Id. at 11-12.)

## II. LEGAL STANDARD

When deciding a motion to dismiss pursuant to Rule 12(b)(6), we “consider only the complaint, exhibits attached to the complaint, [and] matters of public record, as well as undisputedly authentic documents if the complainant’s claims are based upon these documents.” Alpizar-Fallas v. Favero, 908 F.3d 910, 914 (3d Cir. 2018) (quoting Mayer v. Belichick, 605 F.3d 223, 230 (3d Cir. 2010)). “We accept the factual allegations in the complaint as true and construe them in the light most favorable to the plaintiff.” Shorter v. United States, 12 F.4th 366, 371 (3d Cir. 2021) (citing Warren Gen. Hosp. v. Amgen Inc., 643 F.3d 77, 84 (3d Cir. 2011)). However, we “are not bound to accept as true a legal conclusion couched as a factual allegation.” Wood v. Moss, 572 U.S. 744, 755 n.5 (2014) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)).

A plaintiff’s pleading obligation is to set forth “a short and plain statement of the claim,” which “give[s] the defendant ‘fair notice of what the . . . claim is and the grounds upon which it rests.’” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (alteration in original) (first quoting Fed. R. Civ. P. 8(a)(2); and then quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)). The complaint must allege “‘sufficient factual matter to show that the claim is facially plausible,’ thus enabling ‘the court to draw the reasonable inference that the defendant is liable for [the] misconduct alleged.’” Warren Gen. Hosp., 643 F.3d at 84 (quoting Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009)). “The plausibility standard is not akin to a ‘probability requirement,’ but it asks for more than a sheer possibility that a defendant has acted unlawfully.” Iqbal, 556 U.S. at 678 (citing Twombly, 550 U.S. at 556). In the end, we will grant a motion to dismiss brought pursuant to Rule 12(b)(6) if the factual allegations in the complaint are not sufficient “to raise a

right to relief above the speculative level.” Geness v. Admin. Off. of Pa. Cts., 974 F.3d 263, 269 (3d Cir. 2020) (quoting Twombly, 550 U.S. at 555), cert. denied 141 S. Ct. 2670 (2021).

### III. DISCUSSION

#### A. Shotgun Pleadings

Defendants argue that the entire Complaint should be dismissed as an impermissible “shotgun pleading” because the Complaint “is virtually identical to dozens of other complaints that were filed by other plaintiffs across the country around the same time.” (Defs.’ Mem. at 3.) They also argue that the Complaint is a “shotgun pleading” because it contains only a few case-specific factual allegations, namely: (1) Plaintiff’s citizenship; (2) that she was implanted with the TVT product on August 30, 2011; (3) that the TVT mesh is made from polypropylene; and (4) that Plaintiff developed certain complications from the implantation of the TVT product that required a revision procedure. (Compl. ¶¶ 1-4.)

There are four kinds of shotgun pleadings:

(1) “a complaint containing multiple counts where each count adopts the allegations of all preceding counts”; (2) a complaint that is “replete with conclusory, vague, and immaterial facts not obviously connected to any particular cause of action”; (3) a complaint that does “not separat[e] into a different count each cause of action or claim for relief”; and (4) a complaint that “assert[s] multiple claims against multiple defendants without specifying which of the defendants are responsible for which acts or omissions, or which of the defendants the claim is brought against.”

Bartol v. Barrowclough, 251 F. Supp. 3d 855, 859 (E.D. Pa. 2017) (alterations in original) (quoting Weiland v. Palm Beach Cnty. Sheriff’s Off., 792 F.3d 1313, 1321-23 (11th Cir. 2015)). “The ‘unifying characteristic’ of these four types of shotgun pleadings ‘is that they fail to one degree or another, and in one way or another, to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests.’” Id. (quoting Weiland, 792 F.3d at 1323).

The Complaint in this action does not fit into any of these categories. The Complaint identifies only two defendants, separately alleges each of Plaintiff's fourteen claims, specifies the allegations supporting each of those claims, and alleges many facts supporting her allegations that Defendants designed, manufactured, marketed, and sold a product that was defective and caused her injuries. See Drumheller v. Johnson & Johnson, Civ. A. No. 20-6535, 2021 WL 1853407, at \*5 (E.D. Pa. May 10, 2021) (concluding that complaint alleging negligence, strict liability, warranty, and fraud claims arising from the implantation of a pelvic mesh device was not a shotgun pleading because it "allege[d] many facts which, although general, tend to support [plaintiff's] allegations [that] Ethicon designed, manufactured, marketed, and sold a dangerously defective product which caused her injuries"); Murphy v. Hotwire Comm'ns, LLC, Civ. A. No. 19-5901, 2020 WL 2128472, at \*6 (E.D. Pa. May 5, 2020) (denying motion to dismiss with respect to argument that complaint was an impermissible shotgun pleading because the factual allegations of the complaint were "pleaded with enough detail to establish the factual background of the claims"). We conclude, accordingly, that the Complaint sufficiently notifies the Defendants of the claims asserted against them and is not an impermissible "shotgun pleading." See Milo, LLC v. Procaccino, Civ. A. No. 16-5759, 2020 WL 1853499, at \*10 (E.D. Pa. Apr. 13, 2020) (stating that "whether a complaint is an impermissible shotgun pleading . . . [depends] on whether the complaint 'give[s] the defendants adequate notice of the claims against them and the grounds upon which each claim rests.'" (third alteration in original) (quoting M.B. v. Schuylkill Cnty., 375 F. Supp. 3d 574, 587 (E.D. Pa. 2019)).

Defendants also argue that we should dismiss the Complaint as an impermissible "shotgun pleading" because it lacks necessary case-specific information, such as the dates Plaintiff's injuries first manifested and the dates she had any revision surgeries or other medical treatments. They

maintain that the absence of this information makes it impossible for them to ascertain the viability of certain defenses, such as the statute of limitations. However, “because a statute of limitations is an affirmative defense, ‘the burden of establishing its applicability to a particular claim rests with the defendant.’” Pension Tr. Fund for Operating Eng’rs v. Mortg. Asset Securitization Transactions, Inc., 730 F.3d 263, 271 (3d Cir. 2013) (quoting Drennen v. PNC Bank Nat’l Assoc., 622 F.3d 275, 292 (3d Cir. 2010)) (citing Tregenza v. Great Am. Commc’ns Co., 12 F.3d 717, 718 (7th Cir. 1993)). “Indeed, requiring a plaintiff to plead compliance with a statute of limitations would effectively ensure that a timeliness issue would always appear on the face of a complaint, thereby shifting the burden to the plaintiff to negate the applicability of the affirmative defense.” Id. We thus reject Defendant’s argument that Plaintiff’s omission of certain dates from her Complaint renders her Complaint an impermissible shotgun pleading and warrants dismissal of the Complaint. For all of the above reasons, we deny the Motion to Dismiss insofar as it seeks dismissal of the Complaint as an impermissible “shotgun pleading.”

#### B. Manufacturing Defect Claims

Count I of the Complaint asserts a manufacturing defect claim based on a negligence theory and Count III of the Complaint asserts a manufacturing defect claim based on negligence and strict liability theories. Specifically, the Complaint alleges that “[t]he TVT product implanted in Plaintiff was not reasonably safe for its intended use” and that the manufacturing of the TVT product “deviated materially from Defendants’ design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to Plaintiff.” (Compl. ¶ 122.)

The Pennsylvania Supreme Court has “adopted Section 402A of the Restatement (Second) of Torts as the law governing strict products liability actions.” Barton v. Lowe’s Home Ctrs., Inc., 124 A.3d 349, 354 (Pa. Super. Ct. 2015) (citing Webb v. Zern, 220 A.2d 853 (Pa. 1966)). Section

402A provides that “[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer . . . is subject to liability for physical harm thereby caused to the ultimate user or consumer . . . .” Restatement (2d) of Torts, § 402A(1). Thus, in order to state a facially plausible strict liability claim under section 402A, a complaint must allege “that the product was defective, the defect existed when it left the defendant’s hands, and the defect caused the harm.” Id. (citing Riley v. Warren Mfg., Inc., 688 A.2d 221, 224 (Pa. Super. Ct. 1997)). “A manufacturing defect is a deviation from a product’s intended design.” Chandler v. L’Oreal USA, Inc., 774 F. App’x 752, 754 (3d Cir. 2019) (citing Tincher v. Omega Flex, Inc., 104 A.3d 328, 393 (Pa. 2014)). Consequently, “a ‘manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer’s intended result or from other ostensibly identical units of the same product line.” Terrell v. Davol, Inc., Civ. A. No. 13-5074, 2014 WL 3746532, at \*7 (E.D. Pa. July 30, 2014) (quoting Lucas v. City of Visalia, 726 F. Supp. 2d 1149, 1154 (E.D. Cal. 2010)). “The ‘manufacturing defect’ theory posits that ‘a suitable design is in place, but that the manufacturing process has in some way deviated from that design.” Id. (quoting Lucas, 726 F. Supp. 2d at 1155) (citing Phillips v. Cricket Lighters, 841 A.2d 1000, 1019 (Pa. 2003) (Saylor, J., concurring)).

In order to plausibly allege a negligence claim, a complaint must allege “that the defendant had a duty to conform to a certain standard of conduct, that the defendant breached that duty, that such breach caused the injury in question, and actual loss or damage.” Smith, 251 F. Supp. 3d at 852 (quoting Berrier v. Simplicity Mfg., Inc., 563 F.3d 38, 61 (3d Cir. 2009)). In this case, “[t]he existence of a duty to exercise reasonable care in the manufacturing of a product is implied in the supplier-consumer relationship.” Id. at 852 n.5 (citing Tincher, 104 A.3d at 382).

Defendants argue that the Complaint fails to allege facially plausible manufacturing defect claims under both strict liability and negligence theories because it fails to allege the manner in which the TVT product implanted in Plaintiff deviated from Defendant's design and manufacturing specifications such that it was different from the other TVT products manufactured by Defendants and such that it was different from intended.<sup>2</sup>

The Complaint alleges that Defendants failed to manufacture the TVT product as designed and negligently manufactured the TVT product by (1) using "non-medical grade material and inadequate specifications that were not adhered to in the manufacturing of Plaintiff's TVT device[;]" (2) using polypropylene in the manufacturing process; (3) using "laser-cut or mechanical cut polypropylene mesh in [the] manufacturing process . . . [which] contributed to the sharp edges of the device" and resulted in mesh erosion, degradation, and particle loss; and (4) manufacturing the TVT product without a sheath, resulting in an abrasive insertion and possible mesh erosions. (Compl. ¶¶ 124-27.) The Complaint also alleges that the TVT product "that was implanted in Plaintiff deviated from its intended design by utilizing a polypropylene mesh that degrades, contracts, shrinks, frays, cords, migrates, stiffens, hardens, is cytotoxic, causes chronic inflammation, loses pore size with tension, and/or otherwise deforms." (*Id.* ¶ 129.) The Complaint further alleges that "[t]he use of polypropylene in Defendants' manufacturing process for the TVT [product] resulted in an unwanted, chronic immune reaction in Plaintiff" and that Plaintiff was injured as a result of the manufacturing defects. (*Id.* ¶¶ 125, 130.)

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<sup>2</sup> Defendants also argue that we should dismiss Plaintiff's strict liability manufacturing defect claim on the ground that Comment k to Section 402A bars strict liability manufacturing defect claims. However, since we grant Defendants' Motion to Dismiss Plaintiff's manufacturing defect claims based on both strict liability and negligence theories because the Complaint fails to allege a facially plausible manufacturing defect claim based on either of those theories, we need not address that additional argument for dismissing Plaintiff's strict liability manufacturing defect claim.

Defendants argue that these factual allegations do not allege plausible manufacturing defect claims because, while the Complaint alleges that the TVT product implanted in Plaintiff deviated from its intended design, it does not allege that the polypropylene mesh in her TVT product was different from the polypropylene mesh in other TVT products or that the polypropylene used in her device deviated from Defendants' specifications. "The gravamen of [Plaintiff's] complaint is [that the TVT products] are dangerous as designed." Drumheller, 2021 WL 1853407, at \*8. The Complaint alleges a manufacturing defect "due to the use of non-medical grade material and inadequate specifications that were not adhered to in the manufacturing of Plaintiff's TVT [product]." (Compl. ¶ 124.) The Complaint specifies with respect to these "non-medical grade materials" that the TVT product implanted in Plaintiff "deviated from its intended design by utilizing a polypropylene mesh that degrades, contracts, shrinks, frays, cords, migrates, stiffens, hardens, is cytotoxic, causes chronic inflammation, loses pore size with tension, and/or otherwise deforms." (Id. ¶ 129.) However, "[i]n alleging the specifications were 'inadequate' and the product used the defective material 'polypropylene,' [Plaintiff] is really alleging a design defect, not a manufacturing defect." Drumheller, 2021 WL 1853407, at \*8. Since the Complaint specifically alleges that the TVT product, like most pelvic mesh products, is made from polypropylene mesh (Compl. ¶¶ 3, 13, 15), "it is not plausible [that] the design of the product called for a different material and the manufacturer deviated from this design by using polypropylene." Drumheller, 2021 WL 1853407, at \*8. "And if, as [Plaintiff] alleges, the specifications were 'inadequate,' then the specifications were unsuitable as designed." Id.

In addition, the Complaint's allegations regarding the manner in which Defendants "cut the polypropylene mesh either mechanically or by laser . . . [also] goes to the design of the product." Id. As we mentioned above, "[a] manufacturing defect occurs when the product deviates

from the ‘manufacturer’s intended result or from other ostensibly identical units of the same product line.’” Id. (quoting Terrell, 2014 WL 3746532, at \* 7.) The Complaint “does not allege [that] the laser or mechanical cut was unique to the specific product implanted in [Plaintiff]” or to a specific batch of TVT products. Id. Rather, it alleges more generally that cutting the polypropylene mesh either mechanically or by laser created problems in patients implanted with the devices. (Compl. ¶ 128.) Similarly, while the Complaint alleges that the use of “[t]he TVT [product] without a sheath has an abrasive insertion and can lead to mesh erosions” (Id. ¶ 127), it does not allege that the use of the TVT product without a sheath was a deviation from the design of the TVT product or was different from other TVT products manufactured by Defendants.

We conclude that, since the Complaint fails to allege facts showing that the manufacture of the TVT product implanted in Plaintiff deviated from the design of that product or from other TVT products manufactured by Defendants, it fails satisfy the requirement of Federal Rule of Civil Procedure 8(a)(2) that it state facially plausible claims for manufacturing defect under both strict liability and negligence theories. See Twombly, 550 U.S. at 555 (quoting Fed. R. Civ. P. 8(a)(2)); Drumheller, 2021 WL 1853407, at \*8. Accordingly, we grant the Motion to Dismiss with respect to Plaintiff’s manufacturing defect claims in Counts I and III and we dismiss those claims. However, we do so without prejudice because Plaintiff stated at our Hearing that she would amend these claims to add factual allegations that will specify how the TVT product inserted in Plaintiff differed from its design and from other TVT products produced by Defendants, and we will allow her the opportunity to do so. (See 12/2/21 Hr’g Tr. at 6.)

#### C. Strict Liability Design Defect and Failure to Warn Claims

The Complaint asserts strict liability claims for design defect and failure to warn (Counts II and IV). Defendants move to dismiss these claims on the ground that Pennsylvania does not

recognize strict liability claims for design defect and failure to warn with respect to medical devices. Defendants rely on Comment k to Section 402A of the Restatement (Second) of Torts.

As we discussed above, “Pennsylvania has adopted the strict liability formulation set out in Section 402A of the Restatement (Second) of Torts.” Rosenberg v. C.R. Bard, Inc., 387 F. Supp. 3d 572, 576 (E.D. Pa. 2019) (citing Tincher, 104 A.3d at 394-99; Webb, 220 A.2d at 854). A complaint may allege a “defective condition” for purposes of liability under Section 402 “by showing that the product suffered from a design defect [or] failure-to-warn defect . . . .” Id. (citation omitted). However, Section 402A also recognizes that there are “situations where strict liability is unavailable as an avenue of relief for plaintiffs alleging harm caused by a product.” Id. “Specifically, pursuant to comment k of Section 402A, manufacturers of ‘unavoidably unsafe products’ are exempted from strict liability to the extent that the product at issue is ‘properly prepared, and accompanied by proper directions and warning . . . .’” Id. (quoting Restatement (Second) of Torts § 402A cmt. k)). As Comment k explains, there are simply “some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs.” Restatement (Second) of Torts § 402A cmt. k. Thus, Comment k states that products such as “drugs, vaccines, and the like,” are not defective or unreasonably dangerous if “properly prepared, and accompanied by proper directions and warning.” Id.

The Pennsylvania Supreme Court has held that Comment k applies to prescription drugs. See Rosenberg, 387 F. Supp. 3d at 577 (citing Hahn v. Richter, 673 A.2d 888, 890-91 (Pa. 1996)); see also Hahn, 673 A.2d at 890-91 (noting, in a failure to warn case regarding the injection of a prescription medication into the spine that, pursuant to Comment k, the manufacturer’s negligence, is the only recognized basis of liability”); Lance v. Wyeth, 85 A.3d 434, 453 (Pa. 2014) (stating

that “this Court has declined to extend strict liability into the prescription drug arena”). However, the Pennsylvania Supreme Court has not yet determined whether Comment k applies to medical devices such as the TVT product at issue in this case. Rosenberg, 387 F. Supp. 3d at 577. “‘In the absence of a controlling decision by the Pennsylvania Supreme Court, a federal court applying that state’s substantive law must predict how Pennsylvania’s highest court would decide [the] case.’” Id. (alteration in original) (quoting Berrier v. Simplicity Mfg., Inc., 563 F.3d 38, 45-46 (3d Cir. 2009)). Therefore, we must predict whether the Pennsylvania Supreme Court would hold that Comment k bars strict liability claims with respect to prescription medical devices.

The Pennsylvania Superior Court and numerous judges in this Court have predicted that the Pennsylvania Supreme Court would extend Comment k to exclude medical devices from strict liability. See, e.g. Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. Ct. 2006) (stating that there is “no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices”); Drumheller, 2021 WL 1853407, at \*10 (citing Creazzo, 903 A.2d at 31) (additional citations omitted); Rosenberg, 387 F. Supp. 3d at 577-78 (noting that Comment k’s reference to products such as “‘drugs, vaccines, and the like, many of which . . . cannot legally be sold except to physicians, or under the prescription of a physician’ . . . appears to include prescription medical devices because ‘prescription’ medical devices, by definition, are products that require a physician’s prescription, just as ‘prescription’ drugs also, by definition, require a physician’s prescription” (first alteration in original)); Wilson v. Synthes USA Prods., LLC, 116 F. Supp. 3d 463, 467 (E.D. Pa. 2015) (concluding that “comment k of the Restatement (Second) § 402A serves to impose a ban on all strict liability against medical device manufacturers”); Runner v. C.R. Bard, 108 F. Supp. 3d 261, 265-66 (E.D. Pa. 2015) (granting motion to dismiss strict liability design defect and failure to warn claims in accordance with Comment k).

We agree with the reasoning of Drumheller, Creazzo, Rosenberg, Wilson, and Runner and predict that the Pennsylvania Supreme Court would apply Comment k's prohibition of strict liability design defect and strict liability failure to warn claims for prescription drugs to medical devices. Accordingly, we further conclude that neither of Plaintiffs' strict liability design defect and failure to warn claims concerning the TVT product, a medical device, are cognizable under Pennsylvania law, and we grant the Motion to Dismiss as to Plaintiff's strict liability claims for design defect and failure to warn in Counts II and IV with prejudice.

D. Fraud and Misrepresentation Claims

Defendants argue that Plaintiff's claims for common law fraud (Count V), constructive fraud (Count VIII), negligent misrepresentation (Count IX), and fraudulent concealment (Count XII) should be dismissed because these claims are based on allegations that Defendants failed to disclose material information about the safety of the TVT product. Defendants maintain that negligent failure to warn is the only theory on which a plaintiff can recover against the manufacturer of a medical device on the ground that the manufacturer knew about the dangers posed by the device but concealed that information while falsely representing the safety of the device. See Runner, 108 F. Supp. 3d at 268 (“[N]egligence for failure to warn is the sole theory under which a plaintiff can recover against a prescription drug manufacturer when the claim is essentially that the drug company knew of dangers associated with the product but concealed that information while fraudulently misrepresenting the product’s safety.” (citation omitted)). Defendants also argue that these claims should be dismissed because the Complaint does not allege these claims with sufficient specificity to comply with Federal Rule of Civil Procedure 9(b).

1. Common Law Fraud

Count V of the Complaint alleges that Defendants acted fraudulently as follows. “Defendants knowingly, falsely, and actively misrepresented that the TVT product was tested and found to be safe and effective, with actual knowledge that these representations were false.” (Compl. ¶ 168.) The Complaint further alleges that Defendants knew or could have known that the TVT product “caused a large number of complications that were not rare”; “that the safety and efficacy of their TVT product had not been proven with respect to, among other things, the product, its components, its performance and its methods of insertion”; “that there was no evidence that their TVT product was safe and effective and, in fact the evidence that was known or knowable to Defendants was that their TVT product was not safe and effective” but they “continued to represent that their TVT product was safe and effective.” (*Id.* ¶ 170.) The Complaint also alleges that, “[d]espite this knowledge, [Defendants] continued to market and sell their TVT product and associated implantation and removal procedures as being safe and efficacious with evidence to the contrary.” (*Id.* ¶ 171.) The Complaint also alleges that Defendants “intentionally made false claims regarding the true defective nature of the TVT product so that Plaintiff and her implanting physician would rely on these claims and request and purchase Defendants’ TVT product” and that “Defendants knowingly made false claims about the safety and quality of [their] TVT product in the documents and marketing materials [they] provided to the FDA, physicians, and the general public.” (*Id.* ¶¶ 172-73.) The Complaint also specifically alleges that Defendants “knowingly, falsely, and actively misrepresented that the TVT product did not cause chronic injuries, degrade, harden, shrink or contract, fray, cord, curl, lose particles, oxidize, corrode, and/or otherwise deform, with actual knowledge that those representations were false.” (*Id.* ¶ 174.)

The Complaint does not allege merely that Defendants failed to warn of known risks, rather, it also alleges that Defendants made knowing representations regarding the testing of the TVT product, its safety and use, and that it did not cause chronic injuries, degrade or otherwise deform. “[C]ourts have found fraud claims concerning prescription medical devices cognizable if they contain allegations of ‘overt acts,’ such as affirmative misrepresentations, ‘that go beyond a mere failure to warn.’” Shelley v. Ethicon, Inc., Civ. A. No. 12-6862, 2013 WL 3463505, at \*3 (E.D. Pa. July 10, 2013) (quoting James v. Stryker Corp., Civ. A. No. 10-2082, 2011 WL 292240, at \*3-4 (M.D. Pa. Jan. 27, 2011)) (citing Tatum v. Takeda Pharm. N. Am., Inc., Civ. A. No. 12-1114, 2012 WL 5182895, at \*4 (E.D. Pa. Oct. 19, 2012)). Accordingly, we reject Defendants’ argument that Plaintiff’s claim for common law fraud in Count V should be dismissed because negligent failure to warn is the only theory on which a plaintiff can recover against the manufacturer of a medical device that conceals known dangers posed by the device and falsely represents the safety of the device.

Defendants also argue that we should dismiss Plaintiff’s claim for common law fraud in Count V because the Complaint fails to allege fraud with sufficient particularity in accordance with Rule 9(b) of the Federal Rules of Civil Procedure. Rule 9(b) provides that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b). Thus, “[p]ursuant to Rule 9(b), a plaintiff alleging fraud must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the ‘precise misconduct with which [it is] charged.’” Frederico v. Home Depot, 507 F.3d 188, 200 (3d Cir. 2007) (quoting Lum v. Bank of America, 361 F.3d 217, 223-24 (3d Cir. 2004), abrogated on other grounds by Twombly, 550 U.S. at 557). “To satisfy this standard, the plaintiff must plead

or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.” Frederico, 507 F.3d at 200 (citing Lum, 361 F.3d at 224).

While the Complaint alleges that Defendants made specific misrepresentations regarding the nature of the TVT product in their documents and marketing materials, it does not allege the date, time or place in which those misrepresentations were made or otherwise inject precision into the fraud allegations. (See Compl. ¶¶ 172-74.) We conclude, accordingly, that Count V of the Complaint does not plead sufficient facts to comply with Rule 9(b). We thus grant the Motion to Dismiss as to Count V without prejudice to Plaintiff amending the Complaint with respect to Count V.<sup>3</sup>

## 2. Constructive Fraud

Count VIII of the Complaint alleges that Defendants engaged in constructive fraud by suppressing, concealing, omitting and misrepresenting information about the TVT product to

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<sup>3</sup> Plaintiff stated at the Hearing on Defendants’ Motion that she would amend the Complaint in order to allege more specific facts with respect to Count V. (See 12/2/21 Hr’g Tr. at 8.) Thus, we need not address her argument that the Complaint is not required to satisfy Rule 9(b) because the requisite information was within Defendant’s exclusive knowledge and control. See Ohama v. Markowitz, 434 F. Supp. 3d 303, 310 (E.D. Pa. 2020) (stating that “‘courts should be sensitive to the fact that application of [Rule 9(b)] prior to discovery may permit sophisticated defrauders to successfully conceal the details of their fraud. Accordingly, the normally rigorous particularity rule has been relaxed somewhat where the factual information is peculiarly within the defendant’s knowledge or control’” (alteration in original) (quoting In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1418 (3d Cir. 1997))). We note, however, that the Complaint alleges that Defendants made these false representations in “documents and marketing materials [they] provided to the FDA, physicians, and the general public.” (Compl. ¶ 173.) The Complaint also states that “[t]he substantial and particular fraud evidence that has been introduced in several pelvic mesh trials against Defendants will be substantially similar, if not identical to the evidence that will be introduced in this case.” (Id. ¶ 166.) “[I]f the information needed to prove a fraud claim was provided to the FDA, physicians, and the general public, and also produced in several pelvic mesh trials, the [Plaintiff] cannot claim that such information remains within [the] Defendants’ exclusive knowledge and control.” Goodling v. Johnson & Johnson, Civ. A. No. 21-0082, 2022 WL 414285, at \*10 (M.D. Pa. Feb. 10, 2022) (third alteration in original) (quotation omitted).

Plaintiff, the medical community and the FDA. (Compl. ¶ 221.) Specifically, the Complaint alleges that Defendants concealed and suppressed material information that would reveal that the Defendants' TVT product had a higher risk of adverse effects than other devices. (*Id.* ¶ 223.) The Complaint further alleges that Defendants made these misrepresentations in order to induce physicians and Plaintiff to prescribe and purchase the TVT product and Plaintiff and her implanting physician reasonably relied on these misrepresentations. (*Id.* ¶¶ 222, 227-28.) Plaintiff's claim for constructive fraud is therefore grounded on allegations that Defendants knew of the dangers associated with the TVT product and concealed that knowledge while they falsely represented that the TVT product was safe. As we stated above, "negligence for failure to warn is the sole theory under which a plaintiff can recover against a [prescription medical device] manufacturer when the claim is essentially that the [manufacturer] knew of dangers associated with the product but concealed that information while fraudulently misrepresenting the product's safety." *Runner*, 108 F. Supp. 3d at 268 (citing *Kester v. Zimmer Holdings, Inc.*, Civ. A. No. 10–0523, 2010 WL 4103553, at \*4 (W.D. Pa. Oct. 18, 2010)); *see also Kline v. Pfizer, Inc.*, Civ. A. No. 08-3238, 2009 WL 32477, at \*5 (E.D. Pa. Jan. 6, 2009) ("Where, as here, the case is based on failure to warn, negligence is the sole theory upon which a plaintiff may recover against a manufacturer of prescription drugs." (citing *Hahn*, 673 A.2d at 891)). Accordingly, we grant the Motion to Dismiss as to Plaintiff's claim for constructive fraud in Count VIII without prejudice.

### 3. Negligent Misrepresentation

Count IX of the Complaint alleges that Defendants made misrepresentations to Plaintiff, and her physician that the TVT product was suitable for treatment of SUI even though they knew about the TVT product's dangerous characteristics and side effects. Specifically, the Complaint alleges that "Defendants breached their duty to inform physicians . . . regulatory agencies

(including the FDA), and the public of the risks, adverse events, and contraindications of the TVT product . . . [by] representing that Defendants’ TVT product has no serious side effects different from older generations of similar products and/or procedures.” (Id. ¶¶ 239-40.) The Complaint further alleges that Defendants knew that the TVT product has the following dangerous characteristics and side effects:

(a) degradation of the mesh; (b) chronic inflammation and chronic foreign body reaction; (c) mesh that was never intended to be implanted inside the pelvic cavity and is incompatible with the naturally occurring conditions of the vagina including peroxides and bacteria; (d) deformation, rigidity, fraying, roping, cording, and curling of the mesh; (e) loss of pore size with tension; (f) fibrotic bridging leading to scar plate formation and mesh encapsulation; (g) shrinkage/contraction of the encapsulated mesh; and (h) the difficulty and/or impossibility of removing the TVT product.

(Id. ¶ 241.) The Complaint also alleges that “Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed, and sold the TVT product to Plaintiff, carelessly and negligently concealing the harmful effects of the Defendants’ TVT product from Plaintiff, and carelessly and negligently misrepresented the quality, safety and efficacy of the TVT product.” (Id. ¶ 242.) The Complaint further alleges that Defendants made misrepresentations regarding the TVT product’s serious problems to physicians, regulatory agencies, and the public; that Defendants knew that the TVT product had not been proven safe and effective; and that Defendants failed to disclose this information to Plaintiff and the public. (Id. ¶¶ 244, 247-48.)

As these allegations demonstrate, Plaintiff’s claim for negligent misrepresentation essentially alleges that Defendants knew of the dangers associated with the TVT product and concealed that knowledge while they falsely represented that the TVT product was safe. Such allegations cannot support a cognizable claim for negligent misrepresentation because “negligence for failure to warn is the sole theory under which a plaintiff can recover against a [medical device] manufacturer when the claim is essentially that the [manufacturer] knew of dangers associated

with the product but concealed that information while fraudulently misrepresenting the product's safety.” Runner, 108 F. Supp. 3d at 268 (citation omitted). Accordingly, we grant the Motion to Dismiss as to Plaintiff's claim for negligent misrepresentation in Count IX without prejudice.

#### 4. Fraudulent Concealment

The Complaint alleges that Defendants fraudulently concealed material facts regarding the defective nature of the TVT product. (Compl. ¶¶ 298-99.) Specifically, the Complaint alleges that Defendants knew that the TVT product:

caused large numbers of complications that were not rare[,] . . . that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with this device[,] . . . that the safety and efficacy of [the] TVT device had not been proven with respect to, among other things, the product, its components, its performance and its method of insertion[, and . . .] that there was no evidence that its TVT pelvic mesh product was safe and effective.

(Id. ¶ 293.) The Complaint further alleges that Defendants did not disclose these facts and, instead, “continued to market and sell [the] TVT pelvic mesh product and procedure as being safe and efficacious.” (Id. ¶¶ 294-95.) The Complaint also alleges that Defendants represented to physicians, through their physician training program, that the physicians “had sufficient training . . . to minimize or eliminate adverse effects resulting from the TVT device.” (Id. ¶ 295.) The Complaint additionally alleges that Defendants concealed the following material facts from Plaintiff and her physicians: the TVT products were dangerous and defective, they were not effective for their purported use, were not safe for normal use, and could “cause serious consequences to users including permanent and debilitating injuries.” (Id. ¶ 296.) The Complaint also alleges that Defendants intentionally prevented Plaintiff and her implanting physician from learning adverse facts about the TVT product. (Id. ¶ 303.)

These allegations essentially allege that Defendants knew of the dangers associated with the TVT product and concealed that knowledge while they falsely represented that the TVT

product was safe. Such allegations cannot support a cognizable fraudulent concealment claim because “negligence for failure to warn is the sole theory under which a plaintiff can recover against a [medical device] manufacturer when the claim is essentially that the [manufacturer] knew of dangers associated with the product but concealed that information while fraudulently misrepresenting the product’s safety.” Runner, 108 F. Supp. 3d at 268 (citation omitted). Accordingly, we grant the Motion to Dismiss as to Plaintiff’s claim for fraudulent concealment in Count XII without prejudice.

E. Breach of Express Warranty

Count VI of the Complaint asserts a claim for breach of express warranty. The Complaint alleges that “Defendants made assurances . . . to Plaintiff, her implanting physician, the general public, hospitals and health care professionals that the TVT product was safe and reasonably fit for its intended purposes,” that Plaintiff and/or her healthcare providers chose to use the TVT product based on those assurances, and that they reasonably relied on those express warranties. (Compl. ¶¶ 190-91,193.) The Complaint also alleges that Defendants made the following express warranties: “(1) the TVT product is safe and effective; (2) the TVT product does not contract or shrink, or otherwise deform; (3) the TVT product does not degrade; and (4) the TVT product may only cause transient or temporary injuries” (Id. ¶ 199). The Complaint further alleges that Defendants warranted that the TVT was “safer and more effective than other alternative procedures and devices that were on the market on the date the device was implanted in Plaintiff” (id. ¶ 200 (quotation omitted) and “the TVT product may cause ‘transient’ local wound irritation” (id. ¶ 192). The Complaint also alleges that “Defendants breached these express warranties because the TVT product implanted in the Plaintiff was unreasonably dangerous and defective, as described herein, and not as Defendants had represented.” (Id. ¶¶ 194, 201.)

Defendants argue that we should dismiss Plaintiff's breach of express warranty claim because the Complaint does not allege facts that would plausibly state a claim for breach of express warranty. They specifically argue that the Complaint does not allege any specific statement of fact or promise that Defendants made in connection with the TVT product that they breached. "Under Pennsylvania law, an express warranty 'arises out of the representations or promises of the seller . . . and must be directed at consumers in order to induce purchases of the products.'" Esposito v. I-Flow Corp., Civ. A. No. 10-3883, 2011 WL 5041374, at \*6 (E.D. Pa. Oct. 24, 2011) (alteration in original) (quoting Kester v. Zimmer Holdings, Inc., Civ. A. No. 10-0523, 2010 WL 2696467, at \*10 (W.D. Pa. June 1, 2010) ("Kester II"). Thus, in order to state a plausible express warranty claim, a complaint "must establish that the seller made an affirmation of fact or a promise to the buyer which relates to the goods and becomes part of the basis of the bargain." Id. (quotation and citation omitted). "A plaintiff meets the basis of the bargain requirement by proving that she read, heard, saw or knew of the advertisement containing the affirmation of facts or promise." Id. (quoting Kester, 2010 WL 2696467, at \*10); see also Jeter v. Brown & Williamson Tobacco Corp., 113 F. App'x 465, 468 (3d Cir. 2004) (stating that "a plaintiff in a breach of warranty claim must establish that an actual affirmation of fact or a promise formed the basis of the bargain between the seller and the plaintiff. It follows that, in order for an advertisement to form the basis of the bargain, a plaintiff must have seen and relied upon the advertisement" (citing Pa. Cons. Stat. § 2313; Goodman v. PPG Indus., 849 A.2d 1239, 1243 (Pa. Super. Ct. 2004))). "Federal courts applying Pennsylvania law in the medical device context have instructed that this includes such facts as 'the specific source of the alleged warranty . . . and the specific statements made.'" McDonnell v. Flowonix Med. Inc., Civ. A. No. 21-1404, 2022 WL 221612, at \*6 (E.D. Pa. Jan. 25, 2022) (alteration in original) (quoting Dougherty, 2012 WL 2940727, at \*9 n.15). "These

courts have consistently dismissed claims premised solely on conclusory allegations that medical device manufacturers falsely warranted that their products were safe and fit for their intended use.” Id. (citing Shuker v. Smith & Nephew PLC, Civ. A. No. 13-6158, 2015 WL 1475368, at \*12 (E.D. Pa. Mar. 31, 2015); Kester, 2010 WL 2696467, at \*9-10)).

While the Complaint contains allegations regarding the substance of the express warranties on which Plaintiff claims she relied, it does not contain any allegations regarding the specific sources of these warranties, i.e., where Plaintiff “read, heard, [or] saw” those express warranties or how she knew of them. Esposito, 2011 WL 5041374, at \*6. We conclude, accordingly, that the Complaint fails to allege sufficient facts to state a plausible breach of express warranty claim against Defendants and we grant the Motion to Dismiss as to Count VI of the Complaint. However, we grant the Motion to Dismiss as to Count VI without prejudice because Plaintiff stated during the Hearing on this Motion that she would amend the Complaint to allege the specific affirmations of fact or promises that Defendants made related to the TVT product that she contends were breached.<sup>4</sup>

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<sup>4</sup> Defendants also argue that Plaintiffs’ express warranty claim is time-barred pursuant to the four year statute of limitations applicable to breach of warranty claims under Pennsylvania law. See Ruddy v. Polaris Indus., Inc., Civ. A. No. 17-0423, 2022 WL 628416, at \*17 (M.D. Pa. Mar. 3, 2022) (“In Pennsylvania, breach of warranty claims . . . are governed by a four-year statute of limitations.” (citing 13 Pa. Con. Stat. Ann. § 2725(a)). Plaintiff maintains that her breach of warranty claims relate to warranties for future performance, which are not time-barred. See Soutner v. Covidien, LP, Civ. A. No. 17-2178, 2019 WL 3801438, at \*8 (M.D. Pa. Aug. 13, 2019) (“Ordinarily, a cause of action for breach of warranty accrues when the seller makes tender of delivery; however, if the warranty ‘explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance,’ the cause of action accrues when the breach is or should have been discovered.” (citing 13 Pa. Con. Stat. Ann. § 2725(b)). The parties have agreed to undertake expedited discovery in connection with the statute of limitations and Defendants have expressed their intent to file a dispositive motion with respect to Plaintiff’s breach of warranty claims following that discovery, if appropriate. (See 12/2/21 Hr’g Tr. at 17-20.) Accordingly, because we are granting the Motion to Dismiss as to Plaintiffs’ claims for breach of express and implied warranty on other grounds, and because the parties have agreed

F. Breach of Implied Warranty

Count VII of the Complaint asserts a claim for breach of implied warranty. The Complaint alleges that Defendants impliedly warranted that the TVT product was merchantable and fit for the ordinary purposes for which it was intended and that treatment of Plaintiff's SUI was the ordinary purpose for which the TVT product was intended. (Compl. ¶¶ 208-09.) The Complaint also alleges that both Plaintiff and her implanting physician relied on Defendants' implied warranties of merchantability in consenting to the implantation of the TVT product. (*Id.* ¶ 210.) The Complaint further alleges that "Defendants breached these implied warranties of merchantability because the TVT product implanted in the Plaintiff was neither merchantable nor suited for its intended use as warranted," and instead was unreasonably dangerous and defective, resulting in injuries to Plaintiff and placing her health and safety in jeopardy. (*Id.* ¶¶ 213-15.)

Defendants argue that Plaintiff's breach of implied warranty claim in Count VII should be dismissed because Comment k to the Restatement (2d) of Torts § 402A precludes an implied warranty of merchantability in the sale of prescription drugs and many courts have predicted that the Pennsylvania Supreme Court would extend this preclusion to prescription medical devices. "It is well-established under Pennsylvania law that comment k precludes an implied warranty of merchantability in the sale of prescription drugs." *Runner*, 108 F. Supp. 3d at 267-68 (E.D. Pa. 2015) (citing *Makripodis v. Merrell-Dow Pharm., Inc.*, 523 A.2d 374, 376 (Pa. Super. Ct. 1987)). As the Pennsylvania Superior Court explained in *Makripodis*, "[t]he essence of the warranty of merchantability is that the item sold is fit for the ordinary purposes for which such goods are used." 523 A.2d at 376 (citing *Wisniewski v. Great Atl. & Pac. Tea Co.*, 323 A.2d 744, 746-747 (Pa.

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to engage in expedited discovery with respect to the statute of limitations, we do not address Defendants' statute of limitations argument in connection with the instant Motion to Dismiss.

Super. Ct. 1974); 13 Pa. Cons. Stat. § 2314(b)(3)). However, “the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for ‘ordinary purposes.’” Id. at 377. This is because each of the individuals for whom the drugs “are prescribed is a unique organism who must be examined by a physician who is aware of the nature of the patient’s condition as well as the medical history of the patient.” Id. “District courts in this circuit have extended this reasoning to hold that there can be no breach of implied warranty with respect to medical devices because they are ‘unavoidably unsafe products’ under Comment k.” McGrain v. C.R. Bard, Inc., Civ. A. No. 21-1539, 2021 WL 3288601, at \*5 (E.D. Pa. July 30, 2021) (“predict[ing] that the Pennsylvania Supreme Court would bar a claim for breach of the implied warranty of merchantability against a medical device manufacturer” and dismissing breach of implied warranty claim brought against manufacturer of an IVC filter (citing Carson v. Atrium Med. Corp., 191 F. Supp. 3d 473, 478 (W.D. Pa. 2016); Runner, 108 F. Supp. 3d at 268)); see also Mikula v. C.R. Bard, Inc., Civ. A. No. 21-1307, 2021 WL 5989130, at \*6 (W.D. Pa. Dec. 17, 2021) (“Pennsylvania federal courts have applied Makripodis’s reasoning in the medical device realm to dismiss implied warranty claims, including fitness for particular purpose, under comment k.” (citing Carson, 191 F. Supp. 3d 473, 478); Runner, 108 F. Supp. 3d at 268); Kline v. Zimmer Holdings, Inc., Civ. A. No. 13-513, 2013 WL 3279797, at \*6-7 (W.D. Pa. June 27, 2013); Kester, 2010 WL 2696467, at \*11; Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 751-52 (E.D. Pa. 2007)); Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 752-53 (W.D. Pa. 2004))).

Plaintiff asks us not to dismiss this claim because the Pennsylvania Supreme Court has not adopted Comment k with respect to medical devices. Plaintiff relies on Stevens v. C. R. Bard, Inc., Civ. A. No. 17-1388, 2018 WL 692097 (W.D. Pa. Feb. 2, 2018), a products liability action concerning polypropylene mesh. The Stevens court denied the defendant’s motion to dismiss

express and implied warranty claims based on Comment k because the Pennsylvania Supreme Court has not definitively stated that no cause of action exists for breach of any of these warranties when the object warranted is a medical device. Id. at \*8. See also Smith, 251 F. Supp. 3d at 854-55 (denying motion to dismiss breach of implied warranty of merchantability claim in medical device case where “[t]he Third Circuit has endorsed the general understanding that the implied warranty of merchantability and the rule of strict products liability in the Restatement (Second) of Torts § 402A are ‘essentially the same’” (quoting Gumbs v. Int’l Harvester, Inc., 718 F.2d 88, 94 (3d Cir. 1983)) (citing Reese v. Ford Motor Co., 499 F. App’x 163 (3d Cir. 2012))).

We decline to follow Smith and instead conclude that Runner, Makripodis, McGrain, and Mikula accurately state the present law regarding the viability of implied warranty claims asserted in connection with prescription medical devices in Pennsylvania. We therefore predict, like those cases do, that the Pennsylvania Supreme Court would not recognize breach of implied warranty claims in connection with prescription medical devices. Accordingly, we further conclude that Plaintiffs’ implied warranty claim concerning the TVT product, a medical device, is not cognizable under Pennsylvania law and we grant the Motion to Dismiss as to Plaintiff’s breach of implied warranty claim in Count VII with prejudice.

G. Unjust Enrichment

Count XIII of the Complaint alleges that Defendants were unjustly enriched because Plaintiff paid for the TVT product to treat her SUI, Defendants accepted that payment (thus obtaining a financial benefit from Plaintiff), and the TVT product did not cure Plaintiff’s SUI, but caused her chronic injuries. (Id. ¶¶ 318-25.) The Complaint further alleges that it would be inequitable for Defendants to keep the money Plaintiff paid for the TVT product because she did not receive a safe and effective medical device from Defendants. (Id. ¶ 326.)

Defendants argue that we should dismiss Plaintiff's unjust enrichment claim in Count XIII because it fails to state an unjust enrichment claim on which relief can be granted. "To state a claim for unjust enrichment under Pennsylvania law, the plaintiff must allege that (1) he conferred a benefit on the defendant, (2) the defendant knew of the benefit and accepted or retained it, and (3) it would be inequitable to allow the defendant to keep the benefit without paying for it." Whitaker v. Herr Foods, Inc., 198 F. Supp. 3d 476, 492 (E.D. Pa. 2016) (citing Mitchell v. Moore, 729 A.2d 1200, 1203-04 (Pa. Super. Ct. 1999)). Defendants maintain that the Complaint cannot state a plausible claim for unjust enrichment under Pennsylvania law because Plaintiff's claims sound in tort, not contract. "[U]njust enrichment is not a substitute for failed tort claims in Pennsylvania but, instead, will generally be used to imply quasi-contract liability." In re Avandia Mktg., Sales, Practices. & Prods. Liab. Litig., MDL No. 07-1871, 2013 WL 3486907, at \*3 (E.D. Pa. July 10, 2013) (alteration in original) (quoting Zafarana v. Pfizer, Inc., 724 F. Supp. 2d 545, 560-61 (E.D. Pa. 2010)). However, Pennsylvania also recognizes unjust enrichment claims brought as companions to tort claims in some instances. Whitaker, 198 F. Supp. 3d at 492. Thus, there are two categories of unjust enrichment claims under Pennsylvania law:

(1) a quasi-contract theory of liability, in which case the unjust enrichment claim is brought as an alternative to a breach of contract claim; or (2) a theory based on unlawful or improper conduct established by an underlying claim, such as fraud, in which case the unjust enrichment claim is a companion to the underlying claim.

Id. (citing Zafarana, 724 F. Supp. 2d at 561; Torchia v. Torchia, 499 A.2d 581, 582 (Pa. Super. Ct. 1985)). "With respect to the second theory, an unjust enrichment claim may be pled as a companion, not an alternative, to a claim of unlawful or improper conduct as defined by law—e.g., a tort claim." Id. at 493. "In the tort setting, an unjust enrichment claim is essentially another way of stating a traditional tort claim (i.e., if defendant is permitted to keep the benefit of his tortious conduct, he will be unjustly enriched)." Id. (quoting Steamfitters Local Union No. 420

Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 936 (3d Cir.1999)). Here, Plaintiff's claim for unjust enrichment is brought as a companion to her underlying tort claims. As this is a permissible type of unjust enrichment claim, we reject Defendants' argument that Plaintiff's unjust enrichment claim should be dismissed simply because it sounds in tort.

Defendants also argue that Plaintiff's unjust enrichment claim should be dismissed because Plaintiff received and used the TVT product purchased from Defendants and, therefore, they were not unjustly enriched. "In products liability cases, courts in this Circuit applying Pennsylvania law dismiss unjust enrichment claims where the plaintiff received and used the product at issue." Drumheller, 2021 WL 1853407, at \*17; see also McGrain, 2021 WL 3288601, at \*12 ("Courts in this circuit have dismissed unjust enrichment claims in products liability actions where plaintiffs in fact received and used the product they purchased." (citing Mazur v. Milo's Kitchen, LLC, 2013 WL 3245203, at \*10 (W.D. Pa. June 25, 2013)). The Drumheller court granted Defendants' motion to dismiss the unjust enrichment claim in that case because the plaintiff "d[id] not allege she paid for, but did not receive the product at issue; rather she allege[d] her dissatisfaction with the product." 2021 WL 1853407, at \*18. Similarly, the McGrain court granted a motion to dismiss the plaintiff's unjust enrichment claim arising from the IVC filter that had been implanted in the plaintiff's abdomen, concluding that "[b]ecause Plaintiff acknowledges that she received and used Defendants' product, she cannot plausibly state a claim for unjust enrichment." McGrain, 2021 WL 3288601, at \*12. More recently, the court granted a motion to dismiss an unjust enrichment claim in a products liability action arising from the implantation of a pelvic mesh device in Brown v. C.R. Bard, Inc., Civ. A. No. 21-1552, 2022 WL 420914 (E.D. Pa. Feb. 11, 2022). The Brown court noted that unjust enrichment claims have been dismissed "in products liability actions where plaintiffs in fact received and used the product they purchased." Id. at \*12 (quoting McGrain,

2021 WL 3288601, at \*12). The Brown court explained that Court have “reason[ed] that where a plaintiff acknowledges that she received and used the defendants’ product, the defendant cannot be found to have refused to provide such product.” Id. (citing McGrain, 2021 WL 3288601, at \*12). The Brown court dismissed the plaintiff’s unjust enrichment claim with prejudice because “[she] was implanted with the [pelvic mesh device] in October 2010, where it remained for more than six years before being removed in December 2016” and the plaintiff “therefore cannot show that [the defendant] refused to provide a service or product and any amendment would be futile.” Id. (citing McGrain, 2021 WL 3288601, at \*12)).

Here, the Complaint alleges that Plaintiff was implanted with the TVT product in 2011. Thus, accepting the Complaint’s allegations as true, Plaintiff cannot plausibly allege that Defendants refused to provide her with a service or product in exchange for her payment. See Brown 2022 WL 420914, at \*12. We therefore grant the Motion to Dismiss as to Plaintiff’s claim for unjust enrichment in Count XIII of the Complaint. We further conclude that any amendment of Count XIII would be futile, so we grant the Motion to Dismiss as to Count XIII with prejudice.

#### **IV. CONCLUSION**

For the forgoing reasons, we grant the Motion to Dismiss in part and dismiss it in part. We grant the Motion to Dismiss insofar as it seeks dismissal of Plaintiff’s (1) strict liability claims for design defect and failure to warn in Counts II and IV, (2) claim for breach of implied warranty in Count VII, and (3) claim for unjust enrichment in Count XIII and we dismiss those claims with prejudice. We also grant the Motion to Dismiss in so far as it seeks dismissal of Plaintiff’s (1) manufacturing defect claims under the negligence theory in Count I and under both the strict liability and negligence theories in Count III, (2) claims for common law fraud in Count V, (3) breach of express warranty claim in Count VI, (4) constructive fraud claim in Count VIII, (5)

negligent misrepresentation claim in Count IX, and (6) fraudulent concealment claim in Count XII, but we dismiss these claims without prejudice and grant Plaintiff leave to amend the Complaint with respect these claims. Defendants have agreed to withdraw the Motion to Dismiss as to Plaintiff's claims for negligence in Count I (except with respect to negligent manufacturing defect); negligent design defect in Count II; negligent failure to warn in Count IV; and negligent infliction of emotional distress in Count X, and Plaintiff has agreed to amend those claims. Thus, the Motion is withdrawn insofar as it sought dismissal of Count I (except with respect to negligent manufacturing defect), negligent design defect in Count II, negligent failure to warn in Count IV, and Count X. We also dismiss Plaintiff's claims for gross negligence (Count XI) and punitive damages (Count XIV) by agreement of the parties, without prejudice to Plaintiff seeking punitive damages as a remedy. Plaintiff may file a Second Amended Complaint in which she amends her claims for negligence in Count I, negligent design defect in Count II, manufacturing defect in Count III, negligent failure to warn in Count IV, common law fraud in Count V, breach of express warranty in Count VI, constructive fraud in Count VIII, negligent infliction of emotional distress in Count X, and fraudulent concealment in Count XII.

BY THE COURT:

/s/ John R. Padova

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John R. Padova, J.